CLAIMS

What is claimed is:

1. A method of preventing the formation of inhibitory antibodies in a mammal undergoing gene therapy, said method comprising administering to said mammal an immunosuppressive agent in conjunction with said gene therapy.

2. The method of claim 1, wherein said mammal is a human.

3. The method of claim 1, wherein said gene therapy is delivery of a nucleic acid to said mammal, which when expressed in said mammal, serves to correct a genetic defect in said mammal.

4. The method of claim 3, wherein said protein is selected from the group consisting of Factor VII, Factor VIII, Factor IX, Factor X, alpha1-antitrypsinogen, glucuronidase, a sarcoglycan, an interferon, insulin-like growth factor, and erythopoietin.

5. The method of claim 4, wherein said gene therapy is delivery of Factor IX to said mammal.

6. The method of claim 1, wherein said gene therapy is performed by administering a viral vector to said mammal, wherein said viral vector comprises a nucleic acid to be delivered to said human.

7. The method of claim 6, wherein said viral vector is an adeno-associated viral vector.

8. The method of claim 5, wherein said Factor IX is delivered to said mammal using an adeno-associated virus vector.

9. The claim 1, wherein said immunosuppressive agent is selected from the group consisting of cyclophosphamide, FK506, anti-CD40 ligand, CTLA4Ig, cyclosporin, antiB71-B72, and an immunosuppressive steroid.

10. The method of claim 9, wherein said immunosuppressive agent is cyclophosphamide.

11. The method of claim 9, wherein said immunosuppressive agent is FK506.

12. The method of claim 1, wherein said mammal has hemophilia B and said inhibitory antibodies specifically bind with Factor IX protein.